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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,703	12/23/1999	Irena N. MERENKOVA	TETRAGN.002A	7852

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EXAMINER

ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/471,703

Applicant(s)

MERENKOVA, IRENA N.

Examiner

Lisa B. Arthur

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 19 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 34-38,40-60 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 34-38,40-60 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. This action is in response to the paper filed July 19, 2002. Currently, claims 34-38, 40-60 and 69 are pending. All of the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance for the reasons that follow. Any rejections that have not been reiterated are withdrawn in view of the amendments. This action contains new grounds of rejection which have been necessitated by the amendment of the claims. This action is FINAL.

### **NEW GROUNDS OF REJECTION**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 34-38, 40-60 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuppuswamy et al. in view of Hoogendoorn et al.

Kuppuswamy et al. Teach a method for determining the identity of the polymorphic nucleotide in a target sequence having at least two known variants comprising obtaining a sample containing the target sequence, hybridizing a primer upstream of the variant nucleotide, performing a first extension reaction in the absence of a dNTP complementary to the first known variant but in the presence of a dNTP complementary to the second known variant and a second extension reaction in the absence of a dNTP complementary to the second known variant but in the presence of a dNTP complementary to the first known variant (see abstract and page 1144,

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column 2, last three lines through page 1145, column 1, paragraph 1). Kuppuswamy et al. Teach that a DNA fragment containing each of the variant nucleotides is produced by PCR amplification and a primer which hybridizes immediately 5' of the polymorphic site is annealed to the fragments. Extension occurs in the presence of a labeled dNTP complementary to the mutant nucleotide or to the normal nucleotide. Single nucleotide extensions are performed and analyzed by denaturing polyacrylamide gel electrophoresis and autoradiography.

The method of Kuppuswamy et al. is different from the claimed method only in that Kuppuswamy et al. teaches that the dNTP is labeled and that detection of the single nucleotide extension products was performed by detecting the label and does not specifically teach detecting of a length difference by HPLC, capillary electrophoresis, microfluidic analysis or slab gel analysis

However, Hoogendoorn et al. a similar method of wherein the dNTP is not labeled and the extension products are analyzed not by the presence of a label but instead by detecting length differences by HPLC. Specifically, Hoogendoorn et al. teach a method for determining the identity of the polymorphic nucleotide in a target sequence having at least two known variants comprising obtaining a sample containing the target sequence, hybridizing a primer upstream of the variant nucleotide, performing a first extension reaction in the absence of a dNTP complementary to the first known variant but in the presence of a dNTP complementary to the second known variant and a second extension reaction in the absence of a dNTP complementary to the second known variant but in the presence of a dNTP complementary to the first known variant, wherein the dNTP is not labeled or modified (see abstract, Figure 1, page 90, column 2, paragraph 3 and 5 and Table 2). Hoogendoorn et al. teach that ddNTPs are used to terminate

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the extension reaction but also teach that the extension product is analyzed to determine length by HPLC, teaches that the reactions can be multiplexed and that the extension products can be analyzed separately or as pooled samples by HPLC (see page 90).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Kuppuswamy et al. to use unlabeled dNTPs as used in the method of Hoogendoorn et al and to detect extension on the basis of size differences using electrophoresis or chromatography as taught by Hoogendoorn et al. The ordinary artisan would have been motivated to modify Kuppuswamy et al. To use the unlabeled dNTPs and the HPLC detection as taught by Hoogendoorn et al. Rather than the labeled dNTPs and the label detection methods used by Kuppuswamy et al. Because Hoogendoorn et al. Teach that primer extension and HPLC detection of SNPs is simple and has the advantage of being easily automated and requiring no further purification (see Hoogendoorn et al. Abstract). Hoogendoorn et al. further teach that the method can be multiplexed. The ordinary artisan would have immediately seen from Kuppuswamy et al. that the dideoxynucleotides of Hoogendoorn et al. would not be necessary because Kuppuswamy et al. taught a method which used no dideoxynucleotides. Hoogendoorn et al. showed that the label used in Kuppuswamy et al. was not necessary for detection by showing that HPLC could detect and distinguish by size nucleic acids which have been extended by a single nucleotide. Hoogendoorn et al. also taught the advantages of using HPLC for analysis.

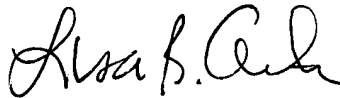
4. No claims are allowable over the prior art.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jehanne Souaya whose telephone number is 308-6565. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
LISA B. ARTHUR  
PRIMARY EXAMINER  
GROUP 1800  
August 27, 2002